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STARCLOSE DEVICE CLOSURE OF FEMORAL ARTERIOTOMY SITE VERSUS MANUAL COMPRESSION IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE: THE CLIPIT TRIAL

i2 Poster Contributions
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Background: The StarClose® Vascular Closure System (Abbott Vascular Devices, Redwood City, CA) is a clip-based device that provides extravascular closure of the femoral arteriotomy site. The favorable safety and efficacy profile of the StarClose has been well described in patients with no documented peripheral arterial disease (PAD). The CLIPIT trial was the first randomized, controlled trial to evaluate the safety and efficacy of the StarClose device in patients with PAD undergoing percutaneous endovascular and coronary procedures.

Methods: This was a single center, prospective, randomized trial evaluating the StarClose device versus standard manual compression in patients with confirmed PAD undergoing percutaneous endovascular and coronary procedures. Patients were randomized in a 1:1 fashion to StarClose or manual compression at the conclusion of the index procedure. All patients received Duplex ultrasounds of the closure site within 7 days of the procedure to evaluate for vascular complications.

Results: 81 total patients were randomized to receive StarClose (n=39) or standard manual compression (n=42). Time to hemostasis was significantly lower in the StarClose group when compared to manual compression (2.98 ± 5.77 minutes versus 19.53 ± 8.74 minutes, p<0.0001). Procedural success was 92.3% (36/39) and device success was 87% (34/39). The rate of major complications in the StarClose group was 7.7% (3/39) versus 7.1% (3/42) in the manual compression group. Pseudoaneurysm or AV fistula was not seen with the StarClose. There were no deaths in either group.

Conclusions: The StarClose Vascular Closure System is safe and effective for closure of femoral arteriotomies in patients with peripheral arterial disease undergoing percutaneous endovascular and coronary procedures. The StarClose device significantly reduced the time to hemostasis when compared to standard manual compression. A large, muticenter, randomized trial is needed to definitively evaluate this extravascular closure system in patients with significant peripheral arterial disease.